

Remarks

Claims 1, 9, 19, and 20 were pending and before the Examiner. By this Amendment, all of the claims have been amended to limit the claims to a tablet or capsule comprising 30 to 90 mg of crystalline telmisartan sodium salt with a melting point of T=245°C ± 5°C. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 1, 2, 4, 5, 9, and 12 to 20, as amended, are now pending and before the Examiner.

The Examiner again provisionally rejected claims 1, 2, 4, 5, 9, and 12 to 20 for nonstatutory obviousness-type double patenting over claims 8 and 9 of Donsbach *et al.* (U.S. Patent No. 6,737,432) in view of Lacourciere *et al.* (American J. Therapeutics 2002, 9(2), pages 111-7).

In response, applicants undertake to file a terminal disclaimer with respect to Donsbach *et al.*, if (1) the instant claims be found otherwise allowable, and (2) applicants determine that Donsbach *et al.* poses a double patenting issue for the claims pending at that time. Since the scope of the claims may change and moot the rejection, there is no need to address this issue at this time, although the applicant recognizes that it need not be withdrawn on this basis alone.

The Examiner again rejected claims 1, 2, 4, 5, 9, and 12 to 20 as allegedly obvious over Lacourciere *et al.* in view of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331).

In response, applicant traverses the rejection. The present application claims priority under 35 U.S.C. § 119(a) to an earlier-filed German application (DE Application No. 103 19 450.9) filed on April 30, 2003, which provides full support for the presently claimed invention for purposes of 35 U.S.C. § 112. In addition, the present application claims priority under 35 U.S.C. § 119(e) to U.S. provisional application U.S.S.N. 60/471,675 filed on May 19, 2003, which is substantially identical to the earlier filed German application. A certified copy of the German priority document was filed with the instant application in addition to with a certified translation of the provisional application.

Because applicant is entitled to rely upon both their foreign priority date of April 30, 2003, and their U.S. provisional application priority date of May 19, 2003, and both of these dates antedate the July 10, 2003, publication date of Donsbach *et al.* (U.S. Patent App. Pub. No.

2003/0130331), Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) is not prior art under 35 U.S.C. § 102(a) or (b) to the present application. Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) can now only qualify as prior art to the present application under 35 U.S.C. § 102(c), and thus *cannot be used* to preclude the patentability of the claimed invention if it was, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C. § 103(c); *see also* MPEP § 706.02(l)(2), Part II. Applicant hereby submits that the present application and Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331), at the time the claimed invention of the present application was made, owned by or subject to an obligation of assignment to the same entity, C.H. Boehringer Sohn AG & Co. KG. C.H. Boehringer Sohn AG & Co. KG is the common owner because it wholly owns Boehringer Ingelheim International GmbH, which is the assignee of the present application, and Boehringer Ingelheim Pharma KG (now renamed Boehringer Ingelheim Pharma GmbH & Co. KG), which is the assignee of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331). Accordingly, Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) cannot be used in an obviousness rejection under 35 U.S.C. § 103(a). Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection because it has been obviated based on the disqualification of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331) as prior art for obviousness purposes.

The Examiner also again rejected claims 1, 2, 4, 5, 9, and 12 to 20 as allegedly obvious over Hauel *et al.* (U.S. Patent No. 5,591,762) in view of Dinnebier *et al.* (J. of Pharmaceutical Sci., 2000, Vol. 89 (11), pages 1465-1479), in further view of Vippagunta *et al.* (Adv. Drug Delivery Rev., 2001, Vol. 48).

In response, applicant has again amended the claims and maintains that such amendments render the Examiner's rejection moot. The cited art do not disclose or suggest the claimed invention of a tablet or capsule comprising 30 to 90 mg of crystalline telmisartan sodium salt with a melting point of $T=245^{\circ}\text{C} \pm 5^{\circ}\text{C}$. Applicant has previously explained that the oral suspension of Example 232 of Hauel *et al.* is largely irrelevant to the instant claims, that Dinnebier *et al.* does not disclose the sodium salt of telmisartan, referring to polymorphic forms of the free acid of telmisartan, but not to any polymorphic forms of the sodium salt of telmisartan, much less that of the instant claimed invention, and that Vippagunta *et al.* does

not mention telmisartan or its sodium salt at all, so its teachings applied to telmisartan is speculative at best. However, it is particularly clear that none of these cited references, teaches or suggest the particular dosage range recited in the claims. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

Applicant submits that all the pending claims are allowable and respectfully solicits a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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